

COMMONWEALTH OF MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH

Clinical Laboratory Program

99 Chauncy Street, 11th Floor, Boston, MA 02111
(617) 753-8439/8438 (617) 753-8240 – Fax

Clinical Laboratory License

REQUIRED DOCUMENTS

☐ **Application for Massachusetts Clinical Laboratory License** - complete, sign, date and return (download from website): <http://www.mass.gov/eohhs/docs/dph/clinical-lab/licensing-application.pdf>.

☐ **Disclosure of Ownership and Control Interest Statement [1513]** - complete, sign, date and return (download 1513 form from website): <http://www.mass.gov/eohhs/docs/dph/clinical-lab/ownership-disclosure.pdf>.

☐ **MUST** be accompanied by Articles of Incorporation or Partnership approved by the Mass. Secretary of State **OR** Foreign Certificate of Approval signed by the Commonwealth of Massachusetts Secretary of State if the organization is not registered in the Commonwealth of Massachusetts

- include a list of corporate officers and/or the Board of Trustees, whichever is appropriate

☐ **Laboratory Personnel Report [CMS 209]** - complete, sign (director signature required), date and return (download CMS 209 form from website): <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS209.pdf>

☐ **CORI form(s)** - complete and return [refer to directions to determine who must submit a form] (download from website): <http://www.mass.gov/eohhs/docs/dph/clinical-lab/licensing-cori-form.pdf>

☐ **List of Laboratory Tests Performed On-Site** - complete and return (download from website): <http://www.mass.gov/eohhs/docs/dph/clinical-lab/clia-laboratory-test-list.pdf>

Failure to provide this information in a timely manner will result in a delay in the processing of information required for the issuance of a Massachusetts Clinical Laboratory license.

☐ **List of Approved Proficiency Testing Programs** - informational only
List of acceptable PT programs can be accessed from the CLIA homepage: <http://www.cms.gov/clia/> by scrolling down to the bottom of the page and clicking on List of Proficiency Testing (PT) Providers



Please note, if you are an independent laboratory applying for CLIA Certification and Initial State Licensure, you will want to contact your Fiscal Intermediary or carrier to request CMS855A or CMS855B or download the forms from the CMS website noted above.